27th meeting of the Homeopathic Medicinal Products Working Group (HMPWG)

May 17–18th 2018
Federal Office of Consumer Protection and Food Safety, Berlin, Germany

Public Report

On 17–18th May 2018 the 27th meeting of the Homeopathic Medicinal Products Working Group (HMPWG) was held in Berlin, Germany, under the Bulgarian European Union Council Presidency. The meeting has been attended by 19 member states, the representative of EMA and the veterinary representative. In addition, the HMPWG mentor of HMA and the German CMDv member attended parts of the meeting.

In absence of candidates for the chair of HMPWG, the veterinary representative, Dr Andrea Golombiewski, was elected as chairperson for the meeting.

No conflicts of interest were declared.

The following issues were discussed:

- **Chairperson of the HMPWG**
  
  Since there has been no nomination, the role and function of the chairperson of HMPWG as well as the role of the interim secretariat was broadly discussed. It was decided to continue the work with the secretariat.

  The composition of the secretariat will be: Astrid Obmann (AT, vice chair in the second half of 2018), Werner Knöss (DE), Emiel van Galen (NL), Eva Mendes (PT) and Andrea Golombiewski (VET). Sandra Holt (SE) informed the group that she will be leaving the secretariat. Additionally, RO, as upcoming presidency in the first half of 2019, is going to be invited to join the secretariat.

- **Minutes of past meetings**
  
  The minutes of the past meetings in Malta (25th meeting) and Uppsala (26th meeting) were adopted. In addition, table of decisons, and list of actions of the 26th meeting were adopted.

- **HMA-HMPWG / interested parties**
  
  Input and questions provided by interested parties were discussed.

- **Legislation**

  *Minimata convention*

  An update on the Minamata convention/EU-regulation 2017/852 on Mercury was given by EMA. An email was sent to the European Commission to find out whether manufacture of HMP is impacted.
**Questionnaire towards definition of HMP**
The outcome of a questionnaire on the interpretation of the definition of a HMP was discussed intensively.

**Q&A document on regulatory and legal issues**
It is intended to develop a Q&A document on legal and regulatory issues.

- **European Pharmacopoeia**
  A written update of the work of HOM and HMM WP had been submitted by EDQM, since no representative was present at the HMPWG meeting.

- **Quality**
  In absence of the chair of the quality sub-working group (SWGQ), the activities were summarised by a member of the group.

**Report of SWGQ and quality documents**
A written report from the Chair of the SWGQ was presented. The last meeting of subgroup took place on October 9th 2017. Question 10 of the Questions & Answers document on microbial limits for non-sterile homeopathic raw materials, stocks, preparations, and products has been adopted for public consultation.

**EDQM meeting on elaboration of monographs (HOM WP)**
UK informed the group that the EDQM is going to organize a meeting with regulatory authorities in June. UK will take part in the meeting and will report on the outcomes.

- **First safe dilution (FSD)**

  **Minutes of sub-working group FSD’s TC meeting**
  The chair of the sub-working group reported from the last telephone conference.

  **Draft 4th List of FSDs**
  For the draft 4th List of FSDs the deadline for comments in public consultation was May 15th 2018. Results of comments will be presented at the next HMPWG meeting.

  **Draft 5th List of FSDs**
  A short final commenting period was decided before adoption for public consultation by written procedure.

  **Draft consolidated list of FSDs**
  A consolidated list on FSD (1st, 2nd, and 3rd) will be published. It was decided to keep the consolidated list in its complete version. Based on the discussion the establishment of an overview document containing both FSD and HU was proposed by DE and a first draft was presented.
Guidance on module 4
Work on a new guidance document on Module 4 has been started within the sub-working group.

- Homeopathic use (HU)

Minutes of subworking group homeopathic use (SWGHU)’s TC meeting
The chair of the sub-working group reported from the last telephone conference.

Preamble of the consolidated list of HU
The overview of comments received on public consultation of the update of the preamble to the consolidated list was discussed. Comments were received from three interested parties. A proposed change for the use of the list for veterinary HMPs was not supported by the SWGHU. The document on the comments was adopted after clarifications from the veterinary representative. The update of the preamble to the consolidated list was adopted.

6th list of stocks of justified HU
The 6th list of stocks of justified homeopathic use and the overview of the comments received on public consultation of draft 6th list of stocks of justified homeopathic use were adopted.

Update of the consolidated list of stocks with a justified HU
The update of the consolidated list of stocks with a justified homeopathic use was adopted. The final list now contains 432 entries. Two versions will be established, one sorted alphabetically according to the German name, the other sorted according to the French name.

Discussion about nosodes
A summary on nosodes was given by a member and discussed within the HMPWG. The sub-group got the mandate to draft a preamble on a document on nosodes with justified homeopathic use (so far only Pyrogenium). The further discussion was postponed to the next HMPWG meeting.

The ad hoc chair expressed her gratitude to all participants for their attendance and contribution to the meeting.

The next meeting of HMPWG will be held on 18–19th October 2018 in Vienna.